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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,640	10/27/2003	Michael J. Cima	TPI-T400C2Z1	3998

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,640	CIMA ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005 and 12 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 3/11/05 has been considered and made of record.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mak et al.(US 5,490,415).

With respect to claim 1, the reference of Mak et al. discloses a device for measuring the transfer of components across a tissue that includes a support plate (4) that supports an array of donor samples. The device includes a tissue specimen (8) that overlays the array of samples and a reservoir plate (6) secured to a side of the tissue specimen opposite the array of samples. The reservoir plate includes an array of reservoirs (26).

With respect to claim 7, the samples are liquid samples.

With respect to claims 8-10, the reference discloses a number of types of tissue samples that can be used (See column 6, lines 43-51).

With respect to claim 13, the reservoir is formed by a passage in the reservoir plate (6).

With respect to claims 14 and 15, the reservoirs include a fluid or solution (See column 6, lines 51-65).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2-6, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al.(US 5,490,415).

The reference of Mak et al. has been discussed above.

Claims 2-6 differ by reciting that each sample of the array differs by a the active component or the additional component.

The reference of Mak et al. discloses that a number of different components of the test sample can be determined including the drug employed, adhesive employed, etc. (See column 3, line 59, to column 4, line 11).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the components within the array of samples for the known and expected result of generating the database discussed by the reference of Mak et al. with respect to permeation experiments.

With respect to claims 11 and 12, while the reference of Mak et al. employs a single membrane when using the array of chambers, the reference suggests that membrane segments could be used (See column 7, lines 60-62).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to segment a single tissue sample using any conventional cutting technique so as to provide the plurality of segments suggested by the reference of Mak et al.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al.(US 5,490,415) in view of Guirguis et al.(US 4,912,057).

The reference of Mak et al. has been discussed above.

Claim 50 differs by reciting that the array of reservoirs has openings on opposing surfaces of the reservoir plate while the reservoir plate (6) of the reference of Mak et al. does not have openings on opposing surfaces.

The reference of Guirguis et al. discloses that it is conventional in the art when supporting a membrane between two fluid containing reservoirs to configure the reservoirs from plates with openings on both surfaces (See Figure 4). The reference discloses that the use of plates with openings on both surfaces to define the fluid holding chambers is an improvement over prior art structures such as that of Mak et al. (See Figures 1 and 2) because it allows access to both chambers during the assay and/or without disturbing the membrane seal (See column 3, lines 28-42; and column 5, lines 34-48).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the reference of Mak et al. such that the reservoir plate (6) includes openings on opposing surfaces for the known and expected result of allowing access to the contents of the reservoir (26) without disturbing the membrane seal between plates (4) and (6).

Terminal Disclaimer

8. The terminal disclaimers filed on 4/12/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,852,526; U.S. Application No. 10/439,943; and U.S. Application No. 10/869,234 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Response to Arguments

9. With respect to the rejection of claims 1, 7-10 and 13-15 under 35 USC 102 (b) over the reference of Mak et al., Applicants argue (See pages 4-5 of the response dated 4/12/05) that the "receiver assembly" (6) of Mak et al. corresponds to the "support plate" of the instant claims and the "donor assembly" (4) of Mak et al. corresponds to the "reservoir plate" of the instant claims. As a result, Applicants conclude that the reference of Mak et al. does not anticipate the instant claims because the tissue specimen of Mak et al. does not **overlay** the array of samples loaded into the support plate.

In response, Applicants' comments are not found to be persuasive because when the device of Mak et al. is assembled as shown in Figures 1 and 3, the device is structurally the same as the device recited in claim 1. That is, membrane (8) of Mak et al. overlays the samples provided in donor assembly (4). Note the order in which the pieces of the device are assembled together carries not patentable weight in apparatus-type claims.

With respect to new claim 50, this new claim limitation has been addressed by the combination of the references of Mak et al. and Guirguis et al.(US 4,912,057).

Applicants further argue that the apparatus of Mak et al. may not be functional in an orientation wherein the "donor assembly" corresponds to the "support plate" of the instant claims because air would become entrapped between the membrane and the samples within the donor receptacles of the donor assembly and result in poor diffusion.

In response, it is not clear how applicants are able to conclude that one would have poor diffusion and/or that air would become entrapped if the device of Mak et al. was inverted such

that the plate (4) was below plate (6). Why wouldn't there be poor diffusion and/or air with respect to the device of Mak et al. when used as disclosed? Additionally, the Examiner maintains that the device disclosed by the reference of Mak et al. and that of the instant claims are structurally the same and statements of intended use, including orientation of the device, carry no patentable weight in apparatus-type claims.

With respect to the 35 USC 103 rejection of claims 2-6, 11 and 12, Applicants merely argue that the information discussed in this rejection fails to make up for the deficiencies previously argued with respect to claim 1 and the 35 USC 102 rejection of record.

In response, the 35 USC 103 rejection was applied against claims 2-6, 11 and 12 to address the additional limitations recited in these claims and was not intended to address the claimed structure of claim 1.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB